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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC. *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counterclaimant.*	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria **PLAINTIFF SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S OPPOSITION TO INTUITIVE'S MOTION TO EXCLUDE DR. RUSSELL LAMB'S EXPERT OPINION TESTIMONY** Hearing: June 8, 2023 Time: 10:00 AM PT Courtroom: Courtroom 5, 17th Floor Judge: The Honorable Vince Chhabria Complaint Filed: May 10, 2021

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MEMORANDUM OF POINTS AND AUTHORITIES

In its motion to exclude certain opinions proffered by Dr. Russell Lamb, Intuitive does not challenge Dr. Lamb's qualifications or whether his testimony would be helpful to the jury as to his opinions on economic issues. For the most part, the motion to exclude focuses on the reliability of his methodology and argues that certain of his opinions are contrary to law.

Reliability requires that the expert's testimony have a reliable basis in the knowledge and experience of the relevant discipline. *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188-89 (9th Cir. 2019). The district court must assess whether the expert has employed in the litigation context the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. *Id.* at 1189. The reliability analysis is "a malleable one tied to the facts of each case," and "district courts are vested with 'broad latitude' to 'decide how to test an expert's reliability' and 'whether or not an expert's relevant testimony is reliable.'" *Murray v. S. Route Mar. SA*, 870 F.3d 915, 922–23 (9th Cir. 2017) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152–53 (1999)).

"Trial courts must exercise reasonable discretion in evaluating and in determining how to evaluate the relevance and reliability of expert opinion testimony." *United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006). A district court serves as "a gatekeeper, not a fact finder." *Id*. at 654. "The test 'is not the correctness of the expert's conclusions but the soundness of his methodology,' and when an expert meets the threshold established by Rule 702, the expert may testify and the fact finder decides how much weight to give that testimony." *Pyramid Techs., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 814 (9th Cir. 2014) (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)). When the methodology is sound, and the evidence relied upon is sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility.

I. Dr. Lamb's economic analyses of the facts and data in this matter are within the scope of his expertise and are reliable for purposes of Rule 702 and *Daubert*.

Intuitive challenges Dr. Lamb's analyses, conclusions and opinions regarding the relevant product markets in this case asserting that he has not reliably applied the SSNIP test. More particularly, Intuitive argues that although Dr. Lamb discusses the SSNIP test in his report, "[h]is report is devoid of any actual application of the test" because he "did not conduct any economic analysis to calculate whether a small but significant price increase on Intuitive's products, such as five percent, would cause a loss in sales volume such that the price increase would be unprofitable." Dkt. 129 at p. 4-5.[1] Intuitive then claims that "Dr. Lamb may not offer opinions about what he speculates the result of a SSNIP test would have been had he performed one." Id. at p. 7. In essence, Intuitive attempts to preclude Dr. Lamb from utilizing the SSNIP framework at all, because he didn't perform a specific SSNIP calculation. Intuitive's approach ignores that Dr. Lamb applied the SSNIP test in a perfectly acceptable manner as an analytical framework, as discussed further below.

A. Dr. Lamb's opinion that minimally invasive soft tissue surgical robots (MIST Surgical Robots) constitute a relevant antitrust product market is supported by, among other factors, his qualitative consideration of the SSNIP test.

"Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one." *Brown Shoe Co. v. United States*, 370 U.S. 294, 336 (1962). Thus, the Ninth Circuit recognizes that "[d]efinition of the relevant market is a factual question 'dependent upon the special characteristics of the industry involved.'" *St. Alphonsus Med. Ctr.–Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 783–84 (9th Cir. 2015).

[1] References to Intuitive's Motion are to the docket entry of the publicly filed brief at Dkt. 129 and the page number within the brief, while references to exhibits attached to the Motion reference the exhibit numbers of the Bass declaration available at Dkt. 129-1. The under-seal Motion and exhibits are available at Dkt. 130-20-23, with Dkt. 130-21 corresponding to Bass Dec. Ex. 1.

Dr. Lamb identifies the so-called "SSNIP" test as one of the tools economists rely upon in defining relevant antitrust product and geographic markets. Bass Dec. Ex. 1, ¶ 27, n. 72. Dr. Lamb explains that:

> [T]he SSNIP test is used by the FTC and the DOJ to define relevant economic markets. The SSNIP test is intended to ascertain whether a hypothetical monopolist can exercise market power in a relevant product or geographic market. If the hypothetical monopolist is able to permanently (that is, in a "non-transitory" way) raise prices for a product or group of products by a "small but significant" amount, usually assumed to be five percent, without losing so much in sales volume that the increase in price is unprofitable, then that product or group of products constitutes a relevant antitrust product market."

Id. Dr. Lamb further points out that the FTC and DOJ recognize that:

> Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition.

Id. Intuitive does not dispute the accuracy of Dr. Lamb's general statements about the SSNIP test or the description of its use by the FTC and DOJ. Dkt. 129 at p. 5.

Dr. Lamb explains the relevance of the SSNIP test's conceptual framework to defining a relevant antitrust market in terms of its use as a methodological tool:

> That is, a relevant market should contain all the products which are substitutable for each other in the face of small but significant, non-transitory price increases; an analysis of the relevant market thus necessarily focuses on an analysis of *economic* substitutability.

Bass Dec. Ex. 1, ¶ 27. Relying on his training and experience in economics, Dr. Lamb researched and analyzed the market for MIST Surgical Robots. Id. Dr. Lamb concluded that there are no economic substitutes for minimally invasive soft tissue surgeries performed with MIST Surgical Robots and that MIST Surgical Robots are a necessary input in performance of those surgeries. Bass Dec. Ex. 1, ¶¶ 26, 27 . Based on his analysis, Dr. Lamb determined that the market for MIST Surgical Robots constitutes a relevant antitrust product market, and that sales of da Vinci surgical robots occur in this relevant antitrust

product market. Bass Dec. Ex. 1, ¶ 27. Lamb's opinion has a reliable basis in his knowledge of and experience in the field of economics.

Contrary to what Intuitive implies in its motion, Dr. Lamb does not purport to quantitatively apply the SSNIP test in the context of this case anywhere in his expert report. *See e.g.,* Bass Dec. Ex. 1, ¶ 29. This is quite understandable because sufficient price change data is often unavailable in a market dominated by one company that does not frequently change its prices, such as Intuitive. Because Dr. Lamb never purports to perform or potentially perform a specific SSNIP calculation that Intuitive complains of, there is simply nothing to exclude.

B. Intuitive's legal authorities are inapplicable and do not preclude the admissibility of Dr. Lamb's opinions regarding the definition of relevant antitrust markets in this case.

Based on the incorrect premise that Dr. Lamb misapplied the SSNIP calculation, Intuitive argues that "[w]hen an expert offers an opinion on market definition, courts routinely exclude expert opinions that do not reliably apply the SSNIP test." Dkt. 129 at p. 4. As support for this proposition, Intuitive cites to *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009). Id. Intuitive's reliance on this case, and other cases cited in its motion, is misplaced.

In *Kentucky Speedway*, the expert entirely failed to consider "a broader range of potential substitutes." *Id.* Dr. Lamb did not ignore the potential substitute for robotic instruments; he extensively analyzed them. Bass Dec. Ex. 1, ¶¶ 29, 31-46. Moreover, in *Kentucky Speedway*, the expert did not employ the SSNIP framework either quantitatively or qualitatively. Rather than evaluating quantitative or qualitative evidence of potential "consumer substitution," the expert simply "looked at average Sprint Cup ticket prices and attendance figures over an eight-year span and concluded that both price and demand increased." *Ky. Speedway*, 588 F.3d at 918. In contrast to the expert in *Ky. Speedway*, Dr. Lamb's analysis does employ the SSNIP conceptual framework to examine practical indicia of economic substitutability, but he does not claim to have defined the relevant antitrust

market through additional quantitative calculations made in accordance with the definition of the SSNIP test.

Intuitive's reliance on *Teradata Corp. v. SAP SE*, 570 F. Supp. 3d 810 (N.D. Cal. 2021) is also misplaced. In *Teradata*, the antitrust expert's methodology for defining the tying product market was challenged because the challenged expert proffered a *quantitative* analysis to corroborate his *qualitative* analysis and claimed to have applied the "hypothetical monopolist" test (*i.e.*, SSNIP) test. *Id.* at 838-39. The district court in *Teradata* excluded the expert's testimony because his quantitative hypothetical monopolist test did not measure the cross-elasticity of demand or the substitutability of products based on reliable quantitative analyses.[2] *Id.* at 841. There is no dispute here that Dr. Lamb performed a comprehensive analysis of demand between different products and markets.[3]

Intuitive also relies on *In re Live Concert Antitrust Litigation*, 863 F. Supp. 2d 966 (C.D. Cal. 2012), contending that the district court in that case "confronted a similar issue." Dkt. 129 at p. 5. Again, Intuitive is mistaken. In *In re Live Concert* , the district court found that the expert's purported market definition was "neither sufficiently reliable nor sufficiently helpful to the trier of fact to warrant admission under Rule 702" because the expert's analysis "fails to comport with his 'chosen methodology' (i.e., the 'SSNIP' methodology) . . . ." *Id.* at 994. Unlike the antitrust expert challenged in *In re Live Concert*, Dr. Lamb does not invoke nor apply the specific calculations called for by the SSNIP methodology, and consequently, the *In re Live Concert* decision has no applicability here.

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[2] The antitrust expert conducted the SSNIP test using aggregate diversion ("ADR") analysis of "Customer Relationship Management" ("CRM") data. *Teradata*, 570 F. Supp. 3d at 839. The district court noted that the data used in the expert's ADR analysis was flawed and that the ADR analysis itself has "rarely been accepted by the courts." *Id*. at 839-841.

[3] Intuitive's reliance on *Allen v. Dairy Mktg. Servs., LLC*, 2013 WL 6909953, at *7, 9 (D. Vt. Dec. 31, 2013) and *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016) is thus misplaced. In *Allen*, the antitrust expert purported to have actually measured a small but significant non-transitory increase in price to support his definition of the relevant geographic market, but in fact failed to calculate a critical loss threshold as part of a SSNIP calculation. *Allen v. Dairy Mktg. Servs., LLC*, 5:09-cv-00230-cr, Dkt. 470 at p. 11 (D. Vt. Dec. 31, 2013). In *Penn State Hershey Med. Ctr.,* an attempted district court application of the SSNIP test was rejected because "its decision reflects neither the proper formulation nor the correct application of that test." 838 F.3d at 336, 339.

C. Dr. Lamb employs reliable methodology for analyzing practical indicia of economic substitutability.

Intuitive complains that Dr. Lamb "did not reliably apply the SSNIP methodology to test his conclusion, instead he just offered circular reasoning that relied on that conclusion as a basis to assume that the SSNIP test would corroborate it." Dkt. 129 at p. 6. Intuitive further argues that "Dr. Lamb's report does not provide a reason why he did not analyze pricing and volume data in the case to properly implement the SSNIP test" and he "has done nothing to perform the calculations needed to know how the marketplace would react to 'a small but significant increase in price.'" Id. Again, this is simply another way of arguing that Dr. Lamb was required to perform a specific quantitative analysis, which is wrong as described above.

Antitrust plaintiffs must define a relevant product market, which must "encompass the product at issue as well as all economic substitutes for the product." *Newcal Indus., Inc. v. Ikon Office Sol.*, 513 F.3d 1038, 1045 (9th Cir. 2008). Including economic substitutes ensures that the relevant product market encompasses the sellers or producers who have the actual or potential ability to deprive each other of significant levels of business. *Pistacchio v. Apple Inc.*, No. 4:20-cv-07034-YGR, 2021 WL 949422, at *1 (N.D. Cal. Mar. 11, 2021). Dr. Lamb sets forth all of the data, documents, and testimony that he uses in his analysis, and provides a fully elaborated and detailed explanation for each component of his analysis.[4] Based upon the analysis of pertinent facts and data, Dr. Lamb concludes that there

[4] There is no "circular reasoning" present in Dr. Lamb's analyses. Dr. Lamb examined numerous factors including sensitivity to price changes, consistent with the SSNIP framework. *See* Bass Dec. Ex. 1, ¶ 30. Dr. Lamb analyzes evidence demonstrating that the availability of laparoscopic instruments as a potential substitute has not disciplined Intuitive's pricing of robotic surgical instruments. Id. Dr. Lamb analyzes evidence demonstrating that surgical robot instruments have distinctive characteristics from laparoscopic surgery instruments. Id. at ¶¶ 18-20, 38-39. Dr. Lamb analyzes evidence demonstrating that surgical robot instruments have distinctive uses from laparoscopic and open surgery instruments. Id. at ¶¶ 10-15. Dr. Lamb analyzes evidence demonstrating that surgical robot surgery customers are distinct from laparoscopic and open surgery customers. Id. at ¶¶ 40-41, 44. Dr. Lamb analyzes evidence establishing that Intuitive manufactures only robotic surgical instruments and does not manufacture laparoscopic or open instruments. Additionally, Dr. Lamb analyzes evidence that Intuitive itself perceived robotic surgical devices as a distinct market that does not include laparoscopic instruments. Id. at ¶¶ 32-34. Dr. Lamb analyzes medical journals and financial analyst reports (produced from

are no economic substitutes for minimally invasive soft tissue surgeries performed with MIST Surgical Robots and that MIST Surgical Robots are a necessary input in performance of those surgeries. Bass Dec. Ex. 1, ¶¶ 27-48.

Questions about the correctness of an expert's conclusions "are a matter of weight, not admissibility." *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1199 (9th Cir. 2014). Any supposed weaknesses in the opinions and methodologies offered by Dr. Lamb based on his using the SSNIP test as a conceptual framework, rather than as a talismanic calculation, are appropriately addressed not by exclusion before trial, but by vigorous cross-examination during trial. Dr. Lamb's market definition opinion should not be excluded.

II. Dr. Lamb's opinion that Intuitive priced above competitive levels and achieved high margins for da Vinci robots and EndoWrist instruments is reliable and admissible expert opinion evidence on the issue of Intuitive's monopoly power.

Intuitive argues that Dr. Lamb's opinions that Intuitive has exercised monopoly power "are inadmissible because they are contrary to law and not based on reliable principles." Dkt. 129 at p. 7. More specifically, Intuitive attacks one of the numerous indications Dr. Lamb relies on to conclude that Intuitive exercises monopoly power in the market for MIST Surgical Robots[5]: charging supracompetitive prices and achieving high margins, well above marginal costs. Id. Intuitive contends that Dr. Lamb's analysis of Intuitive's prices relative to its marginal costs is inadmissible, as a matter of law, because he allegedly did not consider Intuitive's total costs, including fixed costs like research and development. Id.

Intuitive's own files) showing industry recognition that surgical robots are a distinct market. Id. at ¶¶ 83, 89 and n. 201.

[5] Dr. Lamb opines that Intuitive possesses monopoly power in the market for MIST Surgical Robots in the United States during the relevant period. Bass Dec. Ex. 1 at p. 48. In arriving at this opinion, Dr. Lamb analyzed a number of indicia, including (i) Intuitive's domination of the market for MIST Surgical Robots in the United States during the relevant period; (ii) significant barriers to entry into the market for MIST Surgical Robots in the United States during the relevant period; and (iii) Intuitive's prices for the da Vinci surgical robots greatly exceeded marginal costs. Bass Dec. Ex. 1, ¶¶ 80-107.

A. Dr. Lamb's analysis of Intuitive's pricing relative to marginal costs employs reliable methodology recognized in the field of economics to demonstrate supracompetitive pricing.

Experts in economics recognize that one measure of market power is the ability of a firm to price in excess of marginal cost.

> For the competitive firm, price equals marginal cost; for the firm with monopoly power, price exceeds marginal cost. Therefore, a natural way to measure monopoly power is to examine the extent to which the profit-maximizing price exceeds marginal cost.

Bass Dec. Ex. 1, ¶ 99 (citing in n. 240, Pindyck & Rubinfeld (8th edition) at p. 371). Dr. Lamb also cites to the Lerner Index which relies upon marginal cost to measure the degree of monopoly power in his expert report and states:

> In 1934, economist Abba Lerner proposed the price-cost margin as 'the index of the degree of monopoly power,' commonly known as the Lerner Index. Economists often use this index to measure market power, where the larger the Lerner Index is, the greater is the degree of monopoly power.

Bass Dec. Ex. 1, ¶ 99.[6] The Lerner Index is discussed in the treatise by Pindyck & Rubinfeld (8th edition) at p. 371. Id. at ¶99, n. 242.[7] Another standard economic textbook, cited by Dr. Lamb in his expert report, discusses the relationship of price to marginal cost and how that analysis informs determining monopoly power.

> In contrast to a price-taking competitive firm, a monopoly knows that it can set its own price and that the price chosen affects the quantity it sells. A monopoly can set its price above its marginal cost but does not necessarily make a supracompetitive profit. For example, if a monopoly incurs a fixed cost, its profit may be zero (the competitive level) even if its price exceeds its marginal cost. It is common practice to say that whenever a firm can profitably set its price above its marginal cost without making a loss, it has monopoly power or market power.

Bass Dec. Ex. 1, ¶100 (citing at n. 243, Carlton & Perloff at p. 117).

In other words, as Dr. Lamb states in his report, "one indication of lntuitive's exercise of monopoly power in the market for MIST Surgical Robots is the fact that da

[6] The Lerner Index is defined as: "If P = price and C = marginal cost, then the index of the degree of monopoly power is (P-C)/P" see A.P. Lerner, "The Concept of Monopoly and the Measurement of Monopoly Power," The Review of Economic Studies, Vol. I, No.3, 1934, 157-175 at p. 169.

[7] By construction, the Lerner Index is always between zero and one; for a perfectly competitive firm, price equals marginal cost; so, the Lerner's index equals zero.

Vinci robot prices were set well above marginal costs." Bass Dec. Ex. 1, ¶ 102. Dr. Lamb cites to internal Intuitive documents that showed Intuitive's "global Systems business unit earned contribution margins of 65.1 percent and 60.0 percent in 2019 and 2020, respectively." Id. Dr. Lamb's expert report points out that Intuitive itself acknowledges that the prices for da Vinci robots are set well above marginal costs. Bass Dec. Ex. 1, ¶¶ 103-104.

B. Dr. Lamb's analysis is consistent with numerous courts that have held pricing above marginal cost is evidence of supracompetitive pricing.

Assessing a firm's market power in terms of its ability to charge a supracompetitive price is not a novel concept or methodology that Dr. Lamb invented for the purposes of this litigation. Rather it is a well-recognized economic principle that has been applied in many cases. "Market power is defined as the ability to charge a supracompetitive price — a price above a firm's marginal cost." Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice, §§3.1, 3.1a (4th ed. 2011); *Food Lion, LLC v. Dean Foods Co. (In re Se. Milk Antitrust Litig.)*, 739 F.3d 262, 277 (6th Cir. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (holding that "direct evidence of [market] power is available" where a party sold a product "at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins"); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn. 2016) ("prices in a competitive market will tend (perhaps asymptotically) toward marginal cost, so prices substantially above that cost are supracompetitive by definition.").

Intuitive argues that Dr. Lamb's opinion on monopoly power should be excluded as unreliable and contrary to law because he did not take into account fixed costs like research and development. However, even those Federal district courts that have required evidence of fixed costs in addition to marginal cost only do so in specific circumstances where fixed costs are a unique concern. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 563144, at *11 (D. Mass. Jan. 25, 2018) (finding that sunk costs "are relevant to the inquiry because in a market with high fixed costs like the

pharmaceutical industry, 'even competitive prices may exceed marginal cost'"). Even in such an industry, district courts are split as to whether fixed costs are required. *See In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn. 2016) (rejecting brand manufacturers' sunk costs argument because the fact that "brand manufacturers incur enormous fixed costs developing and marketing new drugs . . . does not mean that the price of the brand drug is not supracompetitive," and stating that the "generally accepted economic means of analyzing the probability that given prices are supracompetitive [is] using price and marginal cost").

In its motion to exclude, Intuitive relies heavily on *Kaiser Foundation v. Abbott Laboratories*, 2009 WL 3877513 (C.D. Cal. Oct. 8, 2009). But that case does not deal with whether an expert's testimony where the marginal cost component of the analysis focusing on supracompetitive pricing failed to account for fixed costs was admissible or not. In *Kaiser*, the court also rejected plaintiff's argument that monopoly power was established by the defendant's supracompetitive pricing, which plaintiff sought to prove with nothing more than evidence that defendant's drug costs more than a generic drug. *Kaiser Foundation v. Abbott Laboratories, et al.*, CV 02-2443-JFW, Dkt. 399 at p. 10 (October 8, 2009). The court in *Kaiser* noted that plaintiff's own expert conceded that the pricing difference between a brand name drug and its generic equivalent does not reflect supracompetitive pricing, based on the fact that companies that produce generics do not incur the substantial research and development expenses incurred by companies that develop and produce brand name drugs. Id. There is no discussion in the *Kaiser* decision of marginal costs or the proper legal approach to calculating marginal costs, and no mention of any requirement to include fixed costs as part of a supracompetitive pricing analysis for a robotic device with 99% market share.[8]

[8] Intuitive also cites three other cases in passing: *United States v. Eastman Kodak Co.*, 63 F.3d 95, 109 (2d Cir. 1995), *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 681 n.10 (D.N.J. 2005), and *Carpenter Tech. Corp. v. Allegheny Techs. Inc.*, 2011 WL 4528303, at *12 (E.D. Pa. Sept. 30, 2011). None of these three cases is controlling legal authority in the Ninth Circuit. Additionally, none of these cases present a substantive analysis of the issue raised by Intuitive in challenging Dr. Lamb's monopoly power opinion

In sum, this Court should reject Intuitive's argument that Dr. Lamb's opinion regarding Intuitive's monopoly power in the MIST Surgical Robot market, based in part on his analysis of Intuitive's supracompetitive pricing, is inadmissible as a matter of law. An additional "fixed costs" analysis is not necessary for Dr. Lamb's analysis of supracompetitive pricing to be "reliable" for purposes of Fed. R. Evid. 702.

III. Dr. Lamb properly relies upon Mr. Phil Phillips' opinions as corroborating other evidence cited in Dr. Lamb's report relevant to Intuitive's patient safety claims.

Intuitive argues that Dr. Lamb as an economist is offering opinions about product safety that he is not qualified to offer. Dkt. 129 at p. 10. More specifically, Intuitive claims that Dr. Lamb intends to offer his opinion that "EndoWrists modified by third parties were equally as safe as new instruments manufactured by Intuitive." Dkt. 129 at p. 11. Dr. Lamb is not guilty of the charge Intuitive brings against him.

In his expert report, Dr. Lamb addresses the Intuitive Service Agreement's terms that state that the license to use EndoWrist instruments expires when the designated number of lives have all been used. Bass Dec. Ex. 1, ¶ 128. Dr. Lamb also indicates he understands that Intuitive claims this requirement was necessary due to patient safety concerns associated with allowing third parties to repair its EndoWrist surgical instruments. Id.

Thereafter, Dr. Lamb examines a recent action taken by the FDA with respect to a 510(k) clearance for the marketing of reprocessed Intuitive Surgical da Vinci model S/Si EndoWrist instruments by a company called Iconocare Health ("Iconocare") and references

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focusing on his consideration of Intuitive's da Vinci surgical robot pricing versus marginal costs. For example, in *Kodak* the district court noted that the use of the Lerner index was inappropriate because Kodak film is not a product differentiated from the film sold by its rivals. *Kodak,* 63 F.3d at 109. In *In re Remeron*, the district court found that plaintiffs provided "no evidence of excessive price-cost margins or restricted output but merely rely on the fact that later generic manufacturers could enter the market more cheaply than Remeron's price in order to establish monopoly power." 367 F. Supp. 2d at 682. In *Carpenter Tech.*, the district court made no mention of nor did it make any evidentiary ruling on how to calculate marginal costs, or whether admissibility under the law required calculation or consideration of fixed costs as part of marginal costs. *Carpenter Technology Corp. v Allegheny Technologies, Inc.*, 5:08-cv-02907-LC, Dkt 102 at pp. 23-25 (September 30, 2011)).

the FDA's conclusion as reflected in its September 2022 letter to Iconocare. Bass Dec. Ex. 1, ¶ 129. Based upon a telephone conversation Dr. Lamb had with SIS's regulatory expert, Mr. Philip Phillips, he was aware that Mr. Phillips was also analyzing the FDA's action with respect to Iconocare. Bass Dec. Ex. 1, ¶ 129 and n. 307. Based on that conversation, Dr. Lamb references his understanding of the opinions Mr. Phillips reached about the significance of the FDA's action with respect to Iconocare. Bass Dec. Ex. 1, ¶¶ 129-130.

Dr. Lamb states at paragraph 131 of his report that he is relying on Mr. Phillips opinion regarding the FDA's assessment of the safety of reprocessed EndoWrist surgical instruments as compared to Intuitive's newly manufactured replacement EndoWrist surgical instruments, as well as on the additional evidence he has reviewed that is consistent with Mr. Phillips' conclusions:

> "For the purposes of my analysis contained in this Expert Report, I rely on the opinions of Mr. Philip Phillips regarding the FDA's assessment of the safety of reprocessed EndoWrist surgical instruments as compared to Intuitive's newly manufactured replacement EndoWrist surgical instruments. Additional evidence I have reviewed is consistent with Mr. Phillips' conclusions regarding the FDA's assessment of the safety of reprocessed EndoWrist instruments. For example, at deposition, Nicky Goodson, Senior Director for Service Operations at Intuitive, testified that Intuitive has not done testing of any kind to determine whether refurbished or repaired EndoWrists performed by third-party repairers similar to SIS would be unsafe to use with the da Vinci surgical robot in MIST surgery. Ms. Goodson further testified:
>
> Q. Aside from your personal opinion, do you have any evidence that Endo Wrists repaired or refurbished by Restore or Rebotix have put patients at risk?
> A. No.
>
> Grant Duque, Director of Core Instruments Design Engineering at Intuitive, similarly testified that he was not aware of any testing that had been done on refurbished EndoWrist instruments performed by third-party repairers similar to SIS.[315] Furthermore, at deposition, Dan Jones, Intuitive's Director of External Affairs, testified that when sending letters outlining patient safety claims to hospitals that were using third party repairers to refurbish EndoWrist instruments, he was unaware of the types of tests those third-party repairers were performing to ensure the safety of the EndoWrist instruments they refurbished.[316]"

Bass Dec. Ex. 1, ¶ 131.

It is at this point in Dr. Lamb's report that Intuitive takes issue with his reliance on Mr. Phillips' conclusions in the allegedly offending paragraph 132. Dkt. 129 at p. 10. Dr. Lamb states:

> The evidence discussed above [in ¶¶ 129-131] is consistent with the opinions contained in Mr. Phillips' expert report that, despite Intuitive's claims to the contrary, EndoWrist instruments repaired or reprocessed by third parties such as SIS were equally as safe as the newly manufactured replacement Endo Wrist instruments hospitals were required to purchase directly from Intuitive.[9]

Bass Dec. Ex. 1, ¶ 132. Dr. Lamb stated earlier in his report his understanding of Mr. Phillips' conclusions:

> I understand Mr. Phillips concludes that Iconocare provided performance data to the FDA that demonstrated that the reprocessed devices are as safe and effective as the predicate devices and operate as originally intended. I also understand that Mr. Phillips further asserts that it is not surprising that FDA determined the Iconocare EndoWrist device to be substantially equivalent, as it is virtually identical to the predicate devices in all respects and one would anticipate that they are as safe and effective. Based on Mr. Phillip's analysis of the FDA's recent clearance of reprocessed EndoWrist instruments, I understand Mr. Phillips has concluded that Intuitive's claims that it is unsafe to use EndoWrist surgical instruments more than the maximum number of times imposed by Intuitive appears to be inconsistent with the determination made recently by the FDA.

Bass Dec. Ex. 1, ¶ 130.

Intuitive does not assert that Mr. Phillips' opinions in this case fail to include the conclusions Dr. Lamb references in paragraph 130 of his report. Further, Intuitive does not appear to be seeking to exclude Dr. Lamb's reliance on Mr. Phillips' expert opinion assessing the meaning and significance of the FDA / Iconocare action. Dr. Lamb relies on Mr. Phillips' opinions and other evidence as support for his opinion questioning the legitimacy of Intuitive's product safety justification for tying the expiration of the limited

[9] Intuitive claims that Dr. Phillips does not offer this opinion in this case. Dkt. 129 at p. 10. That is true to the extent that Mr. Phillips' opinion on this topic is not *in haec verba* what Dr. Lamb describes in paragraph 132. Nevertheless, that is the clear import and meaning of Mr. Phillips' assessment of FDA's substantial equivalency finding with respect to Iconocare's reprocessed EndoWrist instrument with a reset counter providing additional uses beyond the original 10 set by Intuitive.

EndoWrist instrument license to the expiration of the limited number of uses Intuitive imposes with its use counter.

Perhaps one might quibble about Dr. Lamb's characterization of Mr. Phillips' opinion referenced in the allegedly offending paragraph 132 in isolation. But that is not a legitimate basis for excluding any portion of Dr. Lamb's opinion (including paragraph 132) in its proper context, for example, as reflected in the preceding paragraphs 129-131 in his report. Intuitive's motion to exclude should be denied as to this issue.

CONCLUSION

For all of the reasons stated above, SIS respectfully requests that the Court deny Intuitive's motion to exclude Dr. Russell Lamb's opinions in this matter.

Dated: April 20, 2023

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